STATE OF MICHIGAN

DEPARTMENT OF LABOR & ECONOMIC GROWTH

OFFICE OF FINANCIAL AND INSURANCE SERVICES

Before the Commissioner of Financial and Insurance Services

In the matter of

XXXXX
Petitioner **File No. 86369-001**

v

Blue Cross Blue Shield of Michigan
Respondent
_____/

Issued and entered
This 23rd day of January 2008
by Ken Ross
Acting Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On November 19, 2007, XXXXX, the authorized representative of XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Services under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq*. The Commissioner reviewed the material submitted and accepted the request on November 28, 2007.

The Commissioner assigned the case to an independent review organization (IRO) because it involved medical issues. The IRO provided its analysis and recommendations to the Commissioner on December 12, 2007.

II
FACTUAL BACKGROUND

The Petitioner is enrolled for group health coverage through Michigan Education Special Services Association (MESSA). Coverage is governed by the "MESSA Tri-Med Group Insurance for School Employees" certificate of coverage. BCBSM underwrites this coverage and MESSA administers it.

The Petitioner has arthritis and instability in several joints. She was treated with injections intended to stimulate ligament growth in those areas. The treatment is called prolotherapy. The injections were administered beginning January 9, 2007 and cost $100.00 to $120.00 per treatment.

BCBSM denied coverage for this care because it classifies the treatment as investigational/experimental for treatment of the Petitioner's condition. The Petitioner appealed BCBSM's denial through the internal grievance process. After a managerial-level conference on September 10, 2007, BCBSM did not change its decision and issued a final adverse determination dated September 20, 2007.

III
ISSUE

Did BCBSM properly deny coverage for the Petitioner's prolotherapy?

IV
ANALYSIS

Petitioner's Argument

The Petitioner suffers from debilitating pain caused by arthritis in her hands (wrists and thumbs), knees, and back. On January 9, 2007 she began receiving prolotherapy that consisted of injection of solution consisting of FDA approved drugs and other pharmaceuticals (10% calcium gluconate, 1% lidocaine, and normal saline solution). The Petitioner believes that this treatment is not experimental and notes that BCBSM has paid for this care in the past. The Petitioner argues that BCBSM should be required to pay for her prolotherapy.

BCBSM's Argument

Under the provisions of the certificate, BCBSM does not pay for experimental treatment or services related to experimental treatment. BCBSM recognizes that that it paid for procedure code 20610 (arthrocentesis aspiration/injection of major joint) for the Petitioner eleven times during 2006. However, the Petitioner's coverage was changed to the MESSA Tri-Med coverage beginning January 1, 2007. At that time, because her physician was a nonpanel/nonparticipating provider, the

Petitioner's claim received closer scrutiny. BCBSM's examination revealed that, while procedure code 20610 is a payable code, the medications used in the Petitioner's prolotherapy are not generally accepted for the treatment of the Petitioner's condition. BCBSM says that this prolotherapy has not been scientifically demonstrated to be as safe and effective as conventional treatment. Therefore, it is an investigational treatment and is not covered.

Commissioner's Review

The certificate sets forth the benefits that are covered. Section XII, *General Conditions of Your Coverage*, provides:

> We do not pay for experimental or investigational drugs or services. Facility services and physician services, including diagnostic tests, which are related to experimental or investigational procedures, are also not payable.

Also, the certificate, in Section I, *The Language of Your Coverage Booklet*, defines "experimental or investigational" as "[a] service that has not been scientifically demonstrated to be as safe and effective for treatment of the patient's condition as conventional or standard treatment."

The question of whether the Petitioner's prolotherapy is considered investigational or experimental in nature was presented to an IRO for analysis as required by section 11(6) of PRIRA, MCL 550.1911(6). The IRO physician reviewer is a doctor of osteopathic medicine who holds an academic appointment, and has been in active practice for more than ten years.

The IRO reviewer explained that prolotherapy is an injection therapy that is used to treat pain and instability of the spine and joints affected by arthritis. The theory behind use of prolotherapy is that weakened ligaments in the affected joints cause pain and that strengthening these ligaments will reduce pain and instability. Prolotherapy consists of repeatedly injecting joints with a solution to cause sclerosis of the ligaments. The solutions in this therapy include a small amount of anesthetic, a diluent such as normal saline solution and one of a number of sclerosing agents. In this case, the Petitioner's doctor used 1% lidocaine, with 10% calcium gluconate as the sclerosing agent, and a normal saline solution.

The IRO reviewer's report noted that:

> [A] search for articles addressing the use of prolotherapy for treatment of spine and peripheral joint pain revealed only one randomized, prospective, double-blinded, placebo-controlled study that addressed the use of dextrose prolotherapy for finger joints. . . .[T]his study found improvement of pain at rest or with gripping. . . .[A]ll other studies failed to demonstrate conclusively that phototherapy injections are superior to placebo injections. . . .[R]ecent reviews of the literature suggest that further investigation with randomized, placebo-controlled studies is needed to determine the efficacy of prolotherapy.

The reviewer concluded that prolotherapy is investigational for treatment of the Petitioner's condition.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner; in a decision to uphold or reverse an adverse determination the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16) (b). The IRO reviewer's analysis is based on extensive expertise and professional judgment and the Commissioner can discern no reason why the recommendation should be rejected in the present case.

The Commissioner accepts the conclusion of the IRO and finds that prolotherapy for treatment of the Petitioner's condition is investigational and therefore is not a covered benefit under the certificate.

V
ORDER

Respondent BCBSM's September 20, 2007, final adverse determination is upheld. BCBSM is not required to cover the Petitioner's January 9, 2007 prolotherapy.

Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review

should be sent to the Commissioner of the Office of Financial and Insurance Services, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.